

§ 520.2042

(ii) In puppies and adult dogs and in lactating bitches after whelping. To prevent reinfection of *Toxocara canis*.

(3) *Limitations*. Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Retreatment of adult dogs may be necessary at monthly intervals as determined by laboratory fecal examinations. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[52 FR 37937, Oct. 13, 1987, as amended at 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993; 66 FR 9650, Feb. 9, 2001; 67 FR 21996, May 2, 2002]

§ 520.2042 Pyrantel pamoate tablets.

(a) *Specifications*. Each tablet contains pyrantel pamoate equivalent to 22.7, 45.4, or 113.5 milligrams of pyrantel base.

(b) *Sponsor*. See No. 017135 in § 510.600(c) of this chapter.

(c) *Conditions of use*. It is used for dogs as follows:

(1) *Amount*. For dogs weighing over 5 pounds, use at least 2.27 milligrams of pyrantel base per pound of body weight; for dogs weighing 5 pounds or less, use at least 4.54 milligrams of pyrantel base per pound of body weight.

(2) *Indications for use*. For removal and control of large roundworms (ascarids) (*Toxocara canis* and *Toxascaris leonina*), and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(3) *Limitations*. Administer orally directly or in a small amount of food. To prevent reinfection of *T. canis* in puppies, lactating bitches after whelping, and adult dogs; treat puppies 2, 3, 4, 6, 8, and 10 weeks of age; treat lactating bitches 2 to 3 weeks after whelping; routinely treat adult dogs monthly. Do not withhold food prior to or after treatment. The presence of these parasites should be confirmed by laboratory fecal examination. A followup fecal examination should be conducted 2 to 4 weeks after first treatment regimen to determine the need for re-treatment. Consult your veterinarian for as-

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sistance in the diagnosis, treatment, and control of parasitism.

[43 FR 52700, Nov. 14, 1978, as amended at 49 FR 22073, May 25, 1984; 57 FR 48163, Oct. 22, 1992; 58 FR 44611, Aug. 24, 1993]

§ 520.2043 Pyrantel pamoate suspension.

(a) *Specifications*. (1) Each milliliter (mL) contains pyrantel pamoate equivalent to 50 milligrams (mg) pyrantel base.

(2) Each mL contains pyrantel pamoate equivalent to 2.27 or 4.54 mg pyrantel base.

(3) Each mL contains pyrantel pamoate equivalent to 4.54 mg pyrantel base.

(b) *Sponsors*. See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) Nos. 000069, 058829, and 059130 for use of the product described in paragraph (a)(1) as in paragraph (d)(1) of this section.

(2) Nos. 000069, 010237, 058829, and 059130 for use of the products described in paragraph (a)(2) as in paragraph (d)(2) of this section.

(3) No. 023851 for use of the product described in paragraph (a)(3) as in paragraph (d)(2) of this section.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses and ponies*. It is used as follows:

(i) *Amount*. 3 mg per pound (lb) body weight as a single dose mixed with the usual grain ration, or by stomach tube or dose syringe.

(ii) *Indications for use*. For the removal and control of mature infections of large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); pinworms (*Oxyuris equi*); large roundworms (*Parascaris equorum*); and small strongyles.

(iii) *Limitations*. Not for use in horses and ponies to be slaughtered for food purposes. When the drug is for administration by stomach tube, it shall be labeled: "Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(2) *Dogs*. It is used as follows:

(i) *Dogs and puppies*—(A) *Amount*. 2.27 mg/lb body weight as a single dose in the animal's feed bowl by itself or mixed in a small quantity of food.

(B) *Indications for use.* For the removal of large roundworms (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*).

(C) *Limitations.* Additional treatment may be required and should be confirmed by fecal examination within 2 to 4 weeks.

(ii) *Dogs, puppies, and lactating bitches after whelping—*(A) *Amount.* 2.27 mg/lb body weight.

(B) *Indications for use.* To prevent reinfections of *T. canis*.

(C) *Limitations.* Administer to puppies at 2, 3, 4, 6, 8, and 10 weeks of age. Administer to lactating bitches 2 to 3 weeks after whelping. Adult dogs kept in heavily contaminated quarters may be treated at monthly intervals.

[67 FR 43248, June 27, 2002, as amended at 68 FR 54803, Sept. 19, 2003; 68 FR 55199, Sept. 23, 2003; 68 FR 55825, Sept. 29, 2003]

§ 520.2044 Pyrantel pamoate paste.

(a) *Specifications.* (1) Each milliliter (mL) contains 180 milligrams (mg) pyrantel base (as pyrantel pamoate).

(2) Each mL contains 226 mg pyrantel base (as pyrantel pamoate).

(3) Each mL contains 171 mg pyrantel base (as pyrantel pamoate).

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 000069 for use of product described in paragraph (a)(1) of this section.

(2) No. 059130 for use of product described in paragraph (a)(2) of this section.

(3) No. 061623 for use of product described in paragraph (a)(3) of this section.

(c) *Conditions of use.* It is used in horses and ponies as follows:

(1) *Amount.* Equivalent of 3 milligrams pyrantel base per pound of body weight.

(2) *Indications for use.* For removal and control of infections from the following mature parasites: large strongyles (*Strongylus vulgaris*, *S. edentatus*, *S. equinus*); small strongyles; pinworms (*Oxyuris equi*); and large roundworms (*Parascaris equorum*).

(3) *Limitations.* Administer as single dose by depositing paste on dorsum of the tongue using the dose syringe. Not for use in horses intended for food. It is

recommended that severely debilitated animals not be treated with this preparation. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

[47 FR 47377, Oct. 26, 1982; 48 FR 3367, Jan. 25, 1983, as amended at 68 FR 13627, Mar. 20, 2003; 68 FR 34533, June 10, 2003]

§ 520.2045 Pyrantel tartrate powder; pyrantel tartrate pellets.

(a) *Specifications.* (1) Pyrantel tartrate powder horse wormer contains 11.3 percent and swine wormer 10.6 percent pyrantel tartrate.

(2) Pyrantel tartrate pellets colt and horse wormer contains 1.25 percent pyrantel tartrate.

(b) *Sponsor.* (1) See No. 000069 in § 510.600(c) of this chapter for conditions of use provided for in paragraphs (d) (1) and (2) of this section.

(2) See No. 051311 in § 510.600(c) of this chapter, for conditions of use provided for in paragraph (d)(3) of this section.

(c) *Related tolerances.* See § 556.560 of this chapter.

(d) *Conditions of use.* It is used in: (1) Horses and ponies:

(i) For the removal and control of infections from the following mature parasites: Large strongyles (*Strongylus vulgaris*, *Strongylus edentatus*, *Strongylus equinus*), small strongyles (*Trichonema* spp., *Triodontophorus*), pinworms (*Oxyuris*), and large roundworms (*Parascaris*).

(ii) It is administered as a single dose at 0.57 gram of pyrantel tartrate per 100 pounds of body weight mixed with the usual grain ration.

(iii) It is recommended that severely debilitated animals not be treated with this drug. Do not administer by stomach tube or dose syringe. The drug should be used immediately after the package is opened.

(iv) Warning: Not for use in horses and ponies to be slaughtered for food purposes.

(2) Swine:

(i) For the removal and control of large roundworms (*Ascaris suum*) and nodular worm (*Oesophagostomum*) infections.

(ii) It is added to feed at 0.4 gram pyrantel tartrate per pound of nonpelleted ration. The ration is administered as a single treatment as the